Section 5 - 510(k) Summary

APR 2 2 2013

510(k) Summary (per 21 CFR 807.92)

Name of Submitter:	BMEYE BV Hoogoorddreef 60 1101 BE Amsterdam the Netherlands
Contact Person	Mr. J van Goudoever, BMEYE BV Tel + 31 20 7512410 Fax + 31 20 7512419
Date Prepared	August 1, 2012
Trade Names	Nexfin Model 2, Trade name CC Nexfin
Classification	Class II
Classification Name	CFR 870.1130, System, measurement, blood pressure, non-invasive, DXN CFR 870.2770, Plethysmograph, impedance, DSB CFR 870.2700, Oximeter, DQA
Predicate	**Nexfin Model 2, K101123**
Device Description	The BMEYE CC Nexfin hemodynamic monitor is a non-invasive monitor that enables the continuous assessment of a patient's hemodynamic function based on the scientific method of Peňáz - Wesseling. The device measures continuous non-invasive blood pressure (Systolic, Diastolic and Mean) and heart rate as well as a Cardiac Output (CO), which is derived, non-invasively, from the blood pressure waveform. The CC Nexfin also enables the simultaneous measurement of SpO2 and SpHb using a pulse-CO oximetry sensor. The operation of the blood pressure, cardiac output, SpO2 and SpHb measurement are identical to the operation in the predicate (K101123).
Intended Use:	The BMEYE CC Nexfin is intended to, non-invasively and continuously, measure blood pressure, hemodynamic parameters, functional saturation of arterial hemoglobin (SpO2), and total hemoglobin concentration (SpHb) in adult patients. The pulse-oximetry component of CC Nexfin is indicated for use during both no motion and motion conditions and for patients who are well or poorly perfused. The CC Nexfin monitor does not feature (physiological) alarms, therefore the continuous availability of pulse-oximetry data should be treated as a series of spot-checks rather than continuous monitoring. The device is intended for use by physicians or other properly trained medical personnel in a hospital or other appropriate clinical setting.
Technology	The device employs identical technology compared to the predicate (K101123) for blood pressure and cardiac output measurement and the measurement of SpHb and SpO2 using the Masimo Rainbow SET technology.

Functional / Safety Testing	The CC Nexfin has successfully undergone safety testing as well as functional testing to demonstrate equivalence to its predicate devices. The following quality assurance measures were applied to the device: • Risk Analysis • Requirements Review • Design reviews • Code Inspections • Verification and Validation • H/W and S/W Implementation Verification Testing of the SpO2 and SpHb functions by Masimo • Biocompatibility Testing • Safety Testing
Conclusion	The results of this testing demonstrates that the device is safe and effective and substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 22, 2013

Edward Lifesciences BMEYE
c/o Mr. Jeroen van Goudoever
Hoogoorddreeef 60
1101 BE Amsterdam
The Netherlands

Re: K122381
Trade/Device Name: Nexfin Model 2
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN, DSB, DQA
Dated: April 3, 2013
Received: April 08, 2013

Dear Mr. van Goudoever:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Nexfin Model 2 (trade name CC Nexfin)

Indications For Use:

The BMEYE CC Nexfin is intended to, non-invasively and continuously, measure blood pressure, hemodynamic parameters, functional saturation of arterial hemoglobin (SpO2), and total hemoglobin concentration (SpHb) in adult patients. The pulse-oximetry component of CC Nexfin is indicated for use during both no motion and motion conditions and for patients who are well or poorly perfused. The CC Nexfin monitor does not feature (physiological) alarms, therefore the continuous availability of pulse-oximetry data should be treated as a series of spot-checks rather than continuous monitoring. The device is intended for use by physicians or other properly trained medical personnel in a hospital or other appropriate clinical setting.

Prescription Use __√_____ **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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